

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 4

REMARKS

Claims 1-29 are pending in the subject application. Applicants have canceled claims 20-24 without prejudice and added new claims 30-34 corresponding thereto. Claims 1-19 and 25-29 have been withdrawn. Support for new claim 30-34 can be found in the specification at, inter alia, page 25, lines 25-35, page 61, lines 32-35 and page 62, lines 1-27. In addition, applicants have replaced the abstract and the specification of the subject application to address certain formalities and make certain formatting changes. Applicants maintain that the substitute abstract and specification do not introduce any new matter. Claims 1-19, 25-29 and 30-34 will be pending, and new claims 30-34 will be under examination in the subject application upon entry of this Amendment.

Applicants annex hereto as **Exhibit C** a marked-up version of the specification to show the changes made relative to the previous version thereof. Applicants further annex hereto as **Exhibit D** a marked-up version of the abstract to show the changes made relative to the previous version thereof.

Applicants respectfully request that, in view of the amendments and remarks made herein, the Examiner withdraw the outstanding rejections.

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 5

Formalities

Abstract

The Examiner objected to the abstract of the disclosure under M.P.E.P. §608.01(b) as being over 150 words in length. In response to the Examiner's objection, applicants annex hereto a substitute abstract as **Exhibit B**. The substitute abstract is under 150 words in length.

Specification

The Examiner objected to the specification as containing drawings not described in the Brief Description of the Figures section. In addition, the Examiner objected to the specification as containing pages not in compliance with 37 C.F.R. 1.52(a)-(c).

In response, applicants point out that sheets 26-47 of the figures have been deleted. In addition, applicants maintain that the substitute specification annexed hereto as **Exhibit A** complies with 37 C.F.R. 1.52(a)-(c).

Sequence Listing

The Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, attached hereto as **Exhibit E**, requires that applicants submit a paper copy and computer readable form of a Sequence Listing, along with a Statement under 37 C.F.R.

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 6

§1.821(f). Accordingly, applicants hereby submit a Sequence Listing, attached hereto as **Exhibit F**, in compliance with the requirements of §1.821-1.825. In addition, applicants submit herewith the Sequence Listing on the enclosed computer diskette. Applicants also submit as **Exhibit G** a Statement In Accordance With 37 C.F.R. §1.821(f) certifying that the contents of the computer readable form and paper copy are the same, and raise no issue of new matter. In addition, the substitute Specification enclosed herewith as **Exhibit A** contains appropriate references to SEQ ID NOS.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 20-24 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response, applicants point out that claims 20-24 have been canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30-34, and respectfully traverse the rejection.

Briefly, claims 30-34 provide a method for determining whether an agent is capable of modulating the binding of a nARIA polypeptide to a receptor selected from the group consisting of erbB2, erbB3 and erbB4.

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 7

Applicants maintain that a representative number of nARIA polypeptides have been set forth in the subject application to enable the instant method. For example, both human and chicken nARIA polypeptides are disclosed at, *inter alia*, page 10 of the specification. Applicants note that disclosure of all possible nARIA polypeptides is not required for establishing enablement, or written description for that matter. Rather all that need be provided is a representative number of such polypeptides. Applicants have done this, and maintain that claims 30-34 are enabled.

The Examiner also rejected claims 20-24 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In response, applicants point out that claims 20-24 have been canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30-34, and respectfully traverse the rejection. Applicants' traversal is based on the reasons set forth above in connection with the Examiner's enablement rejection.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 8

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 20-24 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In response, applicants point out that claims 20-24 have been canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30-34, and respectfully traverse the rejection.

In support of the rejection, the Examiner asserts that the phrases "receptor-affinity derivative" and "appropriate nARIA polypeptide-affinity derivative" are unclear. The Examiner also asserts that claim 22 is substantially duplicative of claim 21.

In response, applicants maintain that new claims 30-34, which correspond to canceled claims 20-24, clearly set forth that which applicants regard as the invention, and in doing so address the Examiner's concerns discussed above.

In view of the above remarks, applicants maintain that new claims 30-34 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 20 and 23 under 35 U.S.C. §102(b)

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 9

as allegedly anticipated by U.S. Patent No. 5,602,096 to Goodearl ("Goodearl").

In response, applicants point out that claims 20 and 23 have been canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30 and 33, and respectfully traverse the rejection.

Again, the claimed invention provides methods for determining whether an agent is capable of modulating the binding of a nARIA polypeptide to a receptor selected from the group consisting of erbB2, erbB3 and erbB4. Contrary to the Examiner's position, this method requires, in relevant part, contacting the nARIA polypeptide with the receptor in the presence of the agent. For a reference to anticipate the instant invention, it would have to teach all the elements thereof.

Clearly, Goodearl fails to do this, and the Examiner has not shown otherwise. According to the Examiner, Goodearl teaches glial growth factors (GGF) that "possess nARIA activity" and competitive assays with GGF and antibodies. Goodearl fails to teach a nARIA polypeptide or any assay involving a nARIA polypeptide. For these reasons, applicants maintain that Goodearl fails to teach each and every element of the claimed method.

In view of the above remarks, applicants maintain that new claims 30 and 33 satisfy the requirements of 35 U.S.C. §102(b)

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 10

Rejection Under 35 U.S.C. §102(e)

The Examiner rejected claims 20-34 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,284,535 B1 ("Role").

In response, applicants point out that claims 20-24 have been canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30-34, and respectfully traverse the rejection.

New claims 30-34 are discussed above, as is the standard for anticipation.

As with Goodearl, Role fails to teach each and every element of the claimed method. Specifically, nowhere does Role disclose "contacting the nARIA polypeptide to a receptor selected from the group consisting of erbB2, erbB3 and erbB4, under conditions permitting the binding of the nARIA polypeptide to the receptor in the absence of the agent."

In view of the above remarks, applicants maintain that new claims 30-34 satisfy the requirements of 35 U.S.C. §102(e).

Rejection Under 35 U.S.C. §102(f)

The Examiner rejected claims 20-24 under 35 U.S.C. §102(f) as allegedly derived from U.S. Patent No. 6,284,535 B1.

In response, applicants point out that claims 20-24 have been

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 11

canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30-34, and respectfully traverse the rejection.

New claims 30-34 are discussed above.

In response to the Examiner's rejection, applicants again point out that nowhere does Role recite "contacting the nARIA polypeptide with the agent and a receptor selected from the group consisting of erbB2, erbB3 and erbB4, under conditions permitting the binding of the nARIA polypeptide to the receptor in the absence of the agent." Rather, this subject matter and the claimed method comprising it, disclosed only in the instant application, are the invention of the three named applicants. Thus, the Examiner's assertion of derivation is without merit.

Applicants maintain that, for the reasons stated above, new claims 30-34 satisfy the requirements of 35 U.S.C. §102(f).

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 20-24 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,602,096 to Goodearl et al. ("Goodearl") in view of U.S. Patent No. 6,284,535 B1.

In response, applicants point out that claims 20-24 have been canceled, rendering the Examiner's rejection thereof moot. Applicants understand the rejection to apply to new claims 30-34, and respectfully traverse the rejection. Applicants maintain

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 12

that the Examiner has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would have been a reasonable expectation that the claimed invention would succeed.

Applicants maintain that the cited references fail to support a *prima facie* case of obviousness of new claims 30-34.

The rejected claims provide methods for determining whether an agent is capable of modulating the binding of a nARIA polypeptide to a receptor selected from erbB2, erbB3 and erbB4. The cited references are discussed above.

Applicants maintain that the cited references, when combined, do not teach or suggest every element of the claims. Specifically, nowhere does either reference teach the binding of a nARIA polypeptide to an erbB2, erbB3 and erbB4 receptor. Given that Goodearl and Role combined do not teach all the elements of new claims 30-34, it follows that these references also fail to create a motive to combine or a reasonable expectation of success.

In view of the above remarks, applicants maintain that the

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 13

Examiner has failed to set forth a *prima facie* case of obviousness, and that accordingly, new claims 30-34 satisfy the requirements of 35 U.S.C. §103(a).

Conclusion

Applicants maintain that new claims 30-34 are in condition for allowance, and thus, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Applicants : Lorna W. Role et al.
U.S. Serial No.: 09/312,596
Filed : May 14, 1999
Page 14

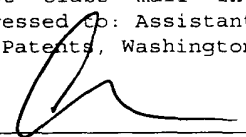
No fee, other than the enclosed \$460.00 for a three-month extension of time, is deemed necessary. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham, LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.


Alan J. Morrison
Reg. No. 37,399

Date

8/27/02

